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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/046,968
Filing Date: January 17, 2002
Appellant(s): HOLTKAMP, REINHOLD

Richard C. Peet
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 2, 2005 appealing from the Office action mailed December 2, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The Examiner relies on seven references as evidence to rebut appellant's arguments regarding the contested claims. The references cited in this Answer are (1) United States Plant Patent Number 13,842, (2) United States Plant Patent Number 13,786, (3) United States Plant Patent Number 13,789, United States Plant Patent Number 13,818, Biology of Plants, 5th ed. by Raven et al. (1992), Genetics, 3rd ed. by Hartl (1994), and Mutation Breeding by van Harten (1998). A copy of each non-patent reference is supplied with this Answer.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The Examiner incorporates by reference the Enablement and Written Description rejections set forth in the final Office Action mailed December 2, 2004. The rejections are located beginning with the second paragraph of Page 2 and ending with the third paragraph on Page 6.

(10) Response to Argument

Enablement

Appellant argues that the disclosure "enables the skilled artisan to produce new multiflorescent African Violet varieties from any [sic] African Violet genetic background." (Appeal Brief, page 9, end of second paragraph.) In truth, the Specification sets forth a method for creating a multiflorescent African Violet plant that is dependent on using the original 'SB 4-2 Muflo' variety, or one of its direct descendants, as at least one of the parent varieties for every multiflorescent African Violet plant created. Appellant has not identified the genetic nature or location of the multiflorescent mutation observed in the 'SB 4-2 Muflo' variety and its progeny. Appellant is unable to introduce the mutated multiflorescent trait into a plant by means other than by sexual crossing. This limitation means that every plant created with the multiflorescent trait is a direct descendant, however far removed, of 'SB 4-2 Muflo'. Appellant is unable to introduce the multiflorescent trait into a plant that is not related to 'SB 4-2 Muflo'.

Appellant argues that the presently rejected claims are enabled because In re Argoudelis holds that deposit procedures adequately satisfy the Section 112 enablement requirement. (Appeal Brief, page 11, end of first full paragraph.) The Examiner agrees that deposit is needed for enablement where the material deposited is necessary to practice the claimed invention. However, the Argoudelis decision was directed towards the timing of deposit, not to the scope of enablement afforded by deposit of an organism.

Appellant argues that by providing "at least one means for producing multiflorescent African Violets" the enablement requirement has been satisfied. (Appeal Brief, Page 12, middle of second paragraph.) Appellant recites In re Fisher, and Spectra-Physics, Inc. v. Coherent, Inc. in support of this argument. However, Fisher holds that claims beyond the scope of the disclosure that might dominate future patentable inventions should only be allowed where those future inventions would be based in some way on Appellant's present teachings. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). Fisher further states that mechanical and electrical inventions may provide such broad enablement, but in cases involving unpredictable factors, such as physiological activity, the "scope of enablement varies inversely with the degree of unpredictability of factors involved." Id.

The CAFC has upheld this distinction in scope of enablement between the predictable and unpredictable arts: "If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment." Spectra-Physics, Inc. v. Coherent, Inc., 3 U.S.P.Q.2d 1737, 1743 (Fed. Cir. 1987)(*See also,* In re Vaeck, 20 U.S.P.Q.2d 1438, 1444 (Fed. Cir. 1991)(holding that broad claims to gene expression in all cyanobacteria were not enabled where the disclosure is limited to disclosure of nine operative species and where the single working example concerns only one species.))

Few arts are as unpredictable as mutation breeding. Mutations come in numerous forms, such as point mutations, deletions, translocations, inversions, extranuclear cytoplasmic mutations and changes in chromosome number. Mutations can arise spontaneously. A standard text on Plant Biology recites, "[m]utations in eukaryotes occur spontaneously at a rate of about 5×10^{-6}

per locus per cell division (that is, 1 mutant gene at a given locus per 200,000 cell divisions.)" Raven, Peter H., Ray F. Evert and Susan E. Eichhorn. Biology of Plants, 5th ed. Worth Publishers, 1992, p. 135. Mutations can also be induced by various forms of radiation or by chemical mutagens.

Predicting particular mutations or the rate at which they occur is highly difficult. *See, e.g.*, Hartl, Daniel L. Genetics, 3rd ed. Jones and Bartlett Publishers, 1994, pp. 474-75 (noting that "three types of damage in DNA are produced by ionizing radiation,") and Mutation Breeding, van Harten, A. M., 1998 pp. 128-133 (illustrating that it is rarely possible to predict mutation frequencies accurately because different plants have different efficiencies in their innate repair mechanisms and require different dose rates of radiation to mutate.) Indeed, in the present case, over 25,000 seeds were incubated in space for six years and twenty seeds displayed the multiflorescence trait. (*See,* Specification, page 7, lines 12-16, page 8, lines 9-11 and page 15 lines 10-20.) Of these 20 plants, only one has been shown to pass on the multiflorescent trait.

The Examiner maintains that the means of producing the claimed invention provided by Appellant does not enable the full scope of the claims as recited. Certainly, Appellant has provided an enabling disclosure to produce multiflorescent African Violet plants using 'SB 4-2 Muflo' or its descendants. However, the appealed claims anticipate and encompass African Violet plants of any parentage. What Appellant has not provided is enablement to produce a multiflorescent African Violet plant from any parentage. Appellant has not identified the nature or location of the multiflorescence genetic trait. Appellant has not isolated the multiflorescence

gene(s). Appellant has not taught how to reproduce the induction of the multiflorescence mutation by mutagenesis; Appellant has not isolated the multiflorescence gene for insertion into an African Violet plant by methods known in the art.

Appellant argues that the Examiner has incorrectly assumed "that all multiflorescent African Violets must be produced or derived from the deposited material" (Appeal Brief, page 14, first paragraph,) and that "other multiflorescent selection produced in Appellant's research program can be used . . . to produce new multiflorescent varieties." (Appeal Brief, page 14, second paragraph.) The Examiner is aware that multiflorescent varieties other than the deposited material can be used to practice the claimed invention; specifically, 'SB 4-4 Muflo' itself, as well as many of its direct descendants may also be used to practice the claimed invention. What the Examiner asserts is that each multiflorescent variety is descended from 'SB 4-2 Muflo' (the trait appears to be dominant) and that Appellant is unable to produce a multiflorescent variety that is not in the direct lineage of 'SB 4-2 Muflo'.

Appellant has recited four varieties created independent of the deposited material, 'EverLove' (United States Plant Patent Number 13,786), 'EverHarmony' (United States Plant Patent Number 13,842), and 'EverPraise' (United States Plant Patent Number 13,789), and 'EverGrace' (United States Plant Patent Number 13,818). (Appellant filed a terminal disclaimer to obviate double patenting rejections between these issued patents and the present case on November 3, 2003.) The parentage of each of the plants recited is set forth in Column 1 of the plant patent directed to that cultivar. The lineage of each plant is also illustrated in FIG. 4 of the present disclosure. 'EverPraise' has 'SB 4-2 Muflo' as its seed parent. 'EverGrace' is a spontaneous mutation (different flower color) of 'EverPraise'. 'EverLove' and 'EverHarmony'

share the seed parent 'P 40/9 white muflo Bie' and the pollen parent 'Q 6/2'. 'P 40/9 white muflo Bie' has 'SB 4-2 Muflo' as a parent; 'Q 6/2' has 'SB 4-2 Muflo' as a grandparent. Accordingly, none of the plants recited was created independent of 'SB 4-2 Muflo'.

Problematically, the appealed claims are directed toward any multiflorescent African Violet plant. Consequently, they would dominate any African Violet plants unrelated to 'SB 4-2 Muflo' that display a multiflorescence. While the Examiner's search of the art has revealed no unrelated multiflorescent African Violet varieties, certainly the potential for their creation or discovery exists. As discussed above, Fisher holds that claims beyond the scope of the disclosure that might dominate future patentable inventions should only be allowed where those future inventions would be based in some way on Appellant's present teachings. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). Appellant has no means of replicating the mutation, and therefore, a subsequent, unrelated multiflorescent African Violet would be the result of efforts independent of what Appellant has presently disclosed.

Finally, Appellant argues that the PTO has granted patents directed to similar subject matter. As an example, Appellant discusses the disclosure and claims of United States Patent Number 5,684,225 ("the '225 patent"). Appellant points out the breadth of Claims 1 and 7, in particular, as examples of broadly enabled claims.

There are several differences in the factual background surrounding the invention of the '225 patent and the present invention. First, as Fig. 3 and Fig. 4 of the '225 patent show, the

parentage of each double-flowering New Guinea Impatiens ("impatiens") variety obtained by Drewlow et al. is not identical. The method of breeding the double-flowered impatiens is not dependent on a single genetic background. Second, unlike the method of the present invention, the method of the '225 patent does not require a double-flowered plant to produce a double-flowered plant. Column 2, lines 40-54 state multiple parentages, all readily available in the art, that can be used to create a double-flowered impatiens plant. In Column 5, lines 14-26, Drewlow et al. estimate the frequency of impatiens plants containing the requisite genetic makeup to practice the claimed method of the invention as 12 in 8000. The patent teaches that "the method" needed to produce double-flowered New Guinea Impatiens plants encompasses multiple methods, can be used with plants of a wider genetic background and is not limited to the use of a single plant and its progeny. In contrast, the frequency of plants capable of reproducing the trait claimed in the present invention is 1 out of all known African Violet plants and some portion of that plant's direct descendants.

Written Description

Appellant argues that the multiflorescence phenotype is described. (Appeal Brief, page 18, second and third paragraphs.) The claims are directed to all multiflorescent African Violet plants; however Appellant has described possession of one reproducible multiflorescent African Violet mutation at the time of filing. Consequently, while the specification provides written support for multiflorescent African Violet plants derived from the one reproducible mutation disclosed, it does not provide support for the broad claims to all multiflorescent African Violet plants.

Appellant considers the Examiner's assertion that "millions of phenotypes are possible and claimed" to be unfounded and irrelevant. (Appeal Brief, page 19, last full paragraph; Office Action of December 2, 2004, end of first full paragraph.) Appellant further argues that the assertion that a skilled artisan would not be able to "predict all of the resulting phenotypes" claimed is also irrelevant. (Appeal Brief, page 20, lines 2-5.) The Examiner disagrees.

The Examiner's assertion that millions of phenotypes are possible and claimed is neither unfounded nor irrelevant to written description. One textbook on mutation breeding asserts: "[t]he final destiny of an induced aberration is difficult to predict. (Mutation Breeding, *supra*, pg. 131, second full paragraph.) The text goes on to note and illustrate that external factors also modify the efficacy of radiation treatments, making their effects unpredictable. (*See*, Mutation Breeding, page 132.)

Appellant sent over 25,000 African Violet seeds into space. (Specification, page 7, lines 12-13.) Of those 25,000 seeds, 20 displayed the multiflorescence trait. (Specification, page 15, lines 10-12.) For 19 of these varieties, no description is given of the number leaf axils displaying multiflorescence or the number of inflorescences per multiflorescent leaf axil. In fact, no phentotypical description at all is provided for these cultivars. Appellant provides no description of the genetic character of the mutations obtained. Appellant does not describe whether the mutation arose at one loci, or multiple loci. Appellant does not provide whether or not each mutated multiflorescent cultivar has mutated at the same location(s), and does not specify

whether or not each mutated multiflorescent cultivar displays additional mutations that might affect the expression of the multiflorescence trait.

Given what is known in the art, as noted in the above paragraph, "considerable variation" between the multiflorescent phenotypes obtained is expected. This variation between species containing the multiflorescent trait is relevant to written description. (See, for example, Interim Written Description Guidelines, pages 61-64, March 1, 2000, updated on the web September 22, 2005, available at http://www.uspto.gov/web/offices/pac/writtendes.pdf) Appellant has not shown possession of every possible multiflorescent African Violet cultivar, as claimed. Appellant has described 'SB 4-2 Muflo", but has not described the other 19 cultivars mentioned except to call them "multiflorescent".

Furthermore, Appellant's description of 'SB 4-2 Muflo" states that it displays from 2 to 3 inflorescences per leaf axil. (Specification, page 10, lines 11-12.) This means that no written description is present in the specification for claims 2 and 3, which are directed to plants where the leaf axil displays "at least 3" or "at least 4" flower stems.

Appellant notes that a skilled plant breeder would be able to predict the percentage of progeny that would display the multiflorescence trait, and that at least 50% of the F_1 generation would display the trait. (Appeal Brief, page 20, first paragraph.) Appellant points to page 16, lines 18-21 of the specification for support. (Appeal Brief, page 20, first paragraph) This would only be the case if the trait in question were a dominant trait. While Appellant asserts the trait is dominant, the evidence in the Specification runs contrary to this assertion, as is illustrated below. Furthermore, Appellant has not characterized the allele in any fashion, has not established

whether the trait is dominant or not, and has not so much as discovered whether the trait is single or the result of multiple genes.

A skilled plant breeder may or may not be able to predict the percentage of African Violets that would display the multiflorescence trait when exposed to cosmic radiation for 6 years, as little information, other than the observed phenotype, is provided regarding the mutation. Furthermore, it appears that a skilled plant breeder would similarly be unable to predict the percentage of multiflorescent African Violets arising from crosses with 'SB 4-2 Muflo' and its progeny, the only cultivars Appellant has described as capable of passing on the multiflorescence trait. (While the Specification notes that other multiflorescent cultivars were obtained from the original group of irradiated plants, these cultivars were most likely chimaeras, as they proved incapable of passing on the trait to their progeny.) While Appellant's Appeal Brief claims that at least 50% of the F_1 generation would display the trait, the citation to lines 18-21 of page 16 of the specification offers nothing to support this assertion. In fact, the examples in the Specification of crosses with 'SB 4-2 Muflo" as a parent tell a different story. The first cross described resulted in no inheritance of the trait in the following generation. (Specification, page 16, lines 4-9.) Two additional crosses resulted in 25% and 20% rates of inheritance. (Specification, page 17, lines 1-7 and lines 12-13.) Only one cross resulted in a greater than 50% (specifically, 60%) rate of inheritance of the trait. (Specification, page 16, lines 12-14.)

Still, the rates of inheritance do not have to be phenomenal for Appellant to show possession at the time of filing. The problem with the appealed claims is that Appellant has

shown possession of only 'SB 4-2 Muflo' and its progeny, rather than all multiflorescent African Violets having this particular characteristic.

Finally, Appellant argues that "[t]he probability of developing a later-rising technology is irrelevant to patentability," and that using the present rationale, "no invention would ever be deemed patentable. The problem with this argument is that Appellant is broadly claiming the multiflorescent trait beyond the scope of what Appellant has shown possession of at the time of filing. Written description certainly cannot be satisfied for the broad claims at issue where development of later technology covered by the claims that is unrelated to what Appellant has shown possession of is foreseeable.

For the above reasons, the Examiner disagrees with the arguments presented by Appellant in the Appeal Brief and respectfully asks the Board to affirm the rejections of record.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

W. C. Haas, J.D.

Patent Examiner, Art Unit 1661

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